K072513

Medvation

510(k) Summary

DEC 17 2007

Submitter Information

GVP Elettronica
Via S. Luccia 65
Caronna Pertusella
Gian Vittorio Pizzi

Contact Person: John Romano
Application Correspondent

Summary Preparation Date: September 5, 2007

Device Information

Trade or Proprietary Name	DM- EMG
Device Common or Usual Name	Hypothermic Therapy System
CDRH Product Nomenclature	Thermal Regulation System (21 CFR 870.5900)
Classification	DWJ

Predicate Device

Medvation has designated the Chill Buster 8001 Portable Electric Blanket manufactured by Thermo Gear, Inc of Tigard Or as the Predicate Device for the DM -EMG

Device Description

The DM –EMG portable warming device is made up of 5 major components

1. Heating mattress SCL-EMG

"Low heating transfer" device made with a strong polyester textile and thousands of micro carbon fibres. The finishing is made with biocompatible PVC. Two on/off switching thermal cut-offs control and maintain warming under the temperature limits provided by the standards. Device construction ensures a soft, light and manageable device, comfortable for the patient. Warming is provided to patient's body by thermal conduction.

2. Cable DC-DC for the connection to the 12Vdc

This cable supplies a very low voltage of 12Vdc to the heating mattress by the 12vdc output of the rescue means. Safety is ensured by an 8A fuse while a green led brightens during working.

3. Rechargeable battery pack NL2024HD22

This is a DM-EMG accessory and it can be supplied under request with its own charger. It is a Class I device, with a nylon bag for portability and the cable has a dedicated connector to the SCL-EMG cable. The battery has about 2, 5 hours of useable life and it allows for patient and infusion bags warming where other power is not available...

4. Dedicated electronic converter VAR100A-EMG

It supplies 12Vac to the SCL-EMG heating mattress when a 230Vac 50 Hz power supply is suitable. It can be connected to the SCL-EMG when inside its DM-ZN1 handbag to warm and maintain warmed infusion bags

5. DM-ZN1 Carrying Case

It is used to carry and protect the SCL-EMG device, especially when it is warming the infusion bags (connected to the battery DC2717-B or 12Vdc of the rescue vehicle (power source).

Intended Use

The DM-EMG portable heating blanket is intended to efficiently keep hypothermia under control and to counteract accidental hypothermia of accident victims and patients during emergency rescue / transport (helicopter, ambulance, automobile, sea and other rescue means). Additionally it can also be used during the routine transport and warming of patients to counteract hypothermia, encountered during a surgical procedure or medical crisis.

Medvation

Technological Comparison

	Submitted Device	Predicate Device
Features	**DM-EMG System**	**Model 8001 System**
Indications For Use	Counteract Hypothermia	Counteract Hypothermia
Function	Low -level heat distributed to patient	Low -level heat distributed to patient
Heat Delivery Mechanism	Conduction	Conduction
Heat Source	Thermal Carbon Fibers and Copper	Thermal Wire in Blanket
	Wires in Blanket	
Electrical Requirements	12vac and 12 vdc / 3-3,5 Amp	12 vdc @3.2 AMP
Heating Element Power	About 35-40 W depending upon	about 40 W
	power source	
Max Heat Presented to Patient	110F	105F
User Heat Output Control	Continuous supply from battery pack	Uncelebrated continuous 20 W - 40W
	converter and DC - DC cable	
Thermal Temperature Cut Off	2 Thermal Cutoffs (91.4F and 104 F)	105F @ blanket wire surface
Alarms	None	None
Circuit Protection	Battery electronic protection UL File	Fused positive battery lead
	0209833. - electronic converter and	
	DC -DC Cable are fuse protected	
Internal Diagnostics	None	None
Safety Agency Approvals	IMQ and cCSAus	TUV Rhineland
EMC Compatibility Testing	EN 60601-1-2 + EN 50366	IEC 601-1-2
Cross- Contamination Protection	Single Use Blanket Cover	Sterile Single Use Blanket Cover
Blanket Material	Biocompatible PVC	Oxford Nylon and Nylon Acrylic
Control Unit Construction		Flame Retardant Polycarbonate
Converter	Latene 7 T -VO UL94 -VO-V2	
Battery	UL File 0209833	
Blanket Cleaning	Wipe with alcohol based disinfectant	machine washable and dryable
System Weight	1.65 lbs blanket with converter	8 lbs
	3.13 lbs blanket with battery	

Medvation

Non Clinical Performance Studies

Formal Studies

The studies reported in this subsection were conducted by the product safety group at IMQ Milan Italy, an Independent firm accredited to test and certify equipment on behalf of numerous worldwide agencies and the DM –EMG is now under CSA approval.

Standards: the DM –EMG has been tested to the following safety standards

EN60601-1	Regulation 10 Automotive
EN60601-1-2	CAN / CSA-C22.2 No.601.1M90
EN60601-2-35	UL 60601-1,2nd edition
EN60601-2-38	cCSAus
EN50366	

DM –EMG Operation Verification

Four (4) separate and distinct lab test were performed by GVP Elettronica srl Caronna P LLA Italy to verify the following operational attributes

USA1. This test illustrates that the DM-EMG warms infusion bags when placed in the carrying case with heating mattress. The 1 liter bag absorbed more heat than a .5 liter bag therefore requires more time to reach 33°C. Warmed surface temperatures were maintained between 29°C and 35°C during the 2.5 hour test.

USA2. This 1 hour test demonstrated that the folded warming blanket stabilized around 32° C in the middle of the pad and in contact with the warmed surface. Additionally this test showed the maximum temperature (+33°C) after the first switch off of the thermal cut off and that a contact temperature over 33°C is reached at the very beginning of warming.
It is important to note that this test was accomplished with the battery pack NL2024HD22

USA3. This 2 hour test maintained surface temperatures around 31 / 32°C and demonstrates the need to maintain the heating mattress insulated from the outside during application.

USA4. This 6 hour test demonstrated that the first thermal cutoff controls temperature and the second thermal cutoff will avoid dangerous temperatures in the event of a default by the first cut off.

In addition this test demonstrated that with maximum power supply from a new and maximum charged battery pack the maximum temperature reached was 40°C

Independent Study

The DM-EMG was used on patients by the Regional Helicopter Rescue Service, Bergamo in Orio al Serio Italy. During Helicopter rescue operations, an on field comparison between active warming with the DM-EMG and passive warming using a thermal reflective blanket was accomplished on 25 patients.

The DM-EMG was used as per the instructions for use manual, and placed on the thorax of the patient

All 25 patients had a mean core temperature <36°C. Those presenting with shivering were actively warmed with DM-EMG. Those without shiver were passively warmed.

Group	# patients	Initial Mean Core Temp	Increase
Active Warming	12	34.6°C	+.6°C
Passive Warming	13	34.8°C	+.3°C

The average mean increase was +.6°C for active warming

In all the Active warming cases a subjective feeling of well being was noted in a short time (5 minutes) and in one case the immediate disappearance of shiver (pediatric patient probably obtained a bigger contact area).

No Complications occurred during Active warming

Conclusions

The DM-EMG performed as intended according to specification against all formal tests completed by IMQ and internal lab tests. The Independent field tests demonstrated efficacy with trauma patients under rescue conditions. The comparison table of technological characteristics demonstrated a substantial technological equivalence compared to the Chillbuster. No issues of safety or effectiveness were found during the afore mentioned tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 7 2007

GVP Elettronica
c/o Mr. John Romano
Medvation Application Correspondent
6 Durham Boat Drive
Washington Crossing, PA 18977

Re: K072513
DM-EMG
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: September 05, 2007
Received: September 11, 2007

Dear Mr. Romano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K072513

Device Name: *DM- EMG*

Indications for Use: The DM-EMG portable heating blanket is intended to efficiently keep hypothermia under control and to counteract accidental hypothermia of accident victims and patients during emergency rescue / transport (helicopter, ambulance, automobile, sea and other rescue means). Additionally it can also be used during the routine transport and warming of patients to counteract hypothermia, encountered during a surgical procedure or medical crisis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Nichols

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072513